

CLAIMS

1. A method for producing a controlled-release pharmaceutical preparation with a particle-containing coating
5 comprising the steps of:

- a) preparing a drug-containing solid core;
- b) suspending a pore-forming agent having a balanced solubility in an aqueous dispersion of a film-forming, essentially water insoluble polymer in order to form a
10 coating suspension having a predetermined amount of solid particles of the pore-forming agent suspended therein
- c) coating the solid core with the obtained suspension; and
- d) drying the coated tablet

15 2. A method according to claim 1, wherein the solubility of the pore-forming agent is below 100 mg/ml, preferably below 50 and most preferably below 30 mg/ml in the aqueous coating dispersion.

20 3. A method according to any one of the claims 1-2, wherein the mean particle size of the pore-forming agent is 0.1-500 μm , preferably is 0.5-100 μm and most preferably 1-25 μm .

25 4. A method according to any one of the claims 1-3, wherein the pore-forming agent is selected from a group consisting of potassium salts, calcium salts, magnesium salts, amino acids, weak acids, carbohydrates, polymers with amino and/or acid functions or a composition wherein at least one of the components is selected from one of these groups.

30 5. A method according to any one of the claims 1-4, wherein the pore-forming agent is potassium bitartrate, creatine, asparagine, glutamine, aspartic acid, glutamic acid, leucin, neroleucine, inosine, isoleucine, magnesium citrate, magnesium phosphate, magnesium carbonate, magnesium hydroxide, magnesium oxide or a composition wherein
35 at least one component is selected from one of these substances.

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Summary

6. A method according to any one of the claims 1-5, wherein the pore-forming agent is chitosan and poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1.

7. A method according to any of the claims 1-6, wherein the water insoluble polymer is selected from one of the groups of cellulose esters, acrylic polymers, polyvinyl acetates, polyvinyl chlorides or a composition wherein at least one component is selected from one of the groups.

8. A method according to any one of the claims 1-7, wherein the coating polymer is ethylcellulose, celluloseacetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylmethacrylate, poly(ethylacrylate, methylmethacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmethacrylate, trimethylaminoethylmethacrylchloride), a block- or copolymer of the polymers or a composition wherein at least one of the components is selected from these polymers.

9. A method according to any one of the claims 1-7, wherein the coating polymer is a copolymer consisting of 50-100% by weight of polyvinyl chloride and 0-50% by weight of polyvinyl acetate.

10. A method according to any one of the claims 1-7, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

11. A method according to any one of the claims 1-10, wherein the solid core includes at least one drug selected from the group consisting of tranquillizers, antibiotics, hypnotics, antihypertensives, antianginas, analgesics, antiinflammatories, neuroleptics, antidiabetics, diuretics, anticholinergics, antihyperacidics or antiepileptics, ACE inhibitors, β -receptor antagonists and agonists, anaesthetics, anorexiant, antiarrhythmics, antide-

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18. A controlled-release pharmaceutical preparation including a drug-containing solid core having a coating thereon, said coating essentially consisting of a water insoluble polymer with a predetermined amount of particles of a water soluble, pore-forming agent dispersed

therein, wherein the pore-forming agent is selected from the group consisting of asparagine, glutamine leucin, ne-
roleucine, isoleucine, magnesium phosphate, magnesium
carbonate, magnesium hydroxide, chitosan and poly(butyl
5 methacrylate, (2-dimethyl aminoethyl) methacrylate,
methyl methacrylate) 1:2:1 or a composition wherein at
least one component is selected from one of these sub-
stances.

19. Preparation according to any one of the claims
17 or 18, wherein the amount of the pore-forming agent is
40-95, preferably 50-90% and most preferably 55-88 % by
weight of the total weight of the dry coating.

20. Preparation according to any one of the claims
17-19 wherein the polymer is ethylcellulose, cellulose-
15 acetate, celluloseacetatebutyrate, celluloseacetatepropi-
onate, nitrocellulose, polymethylmethacrylate,
poly(ethylacrylate, methylmetacrylate), polyvinylacetate,
polyvinylchloride, polyethylene, polyisobutylene,
poly(ethylacrylate, methylmetacrylate, trimethylamo-
20 nioethylmetacrylatchloride), a block- or copolymer of the
polymers or a composition wherein at least one of the
components is selected from these polymers.

21. Preparation according to any one of the claims
17-19, wherein the coating polymer is a copolymer con-
25 sisting of 50-100% by weight of polyvinyl chloride and 0-
50% by weight of polyvinyl acetate.

22. Preparation according to claim 17-19, wherein
the coating polymer is a copolymer consisting of 80-95%
by weight of polyvinylchloride, 0,5-19% by weight of
30 polyvinylacetate and 0,5-10% by weight of polyvinylalco-
hol.

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